

Guideline for Review and Approval of Animal Study Proposals

The standard method for review and approval of Animal Study Proposals (ASP) by the NIH Animal Care and Use Committees (ACUC) is through the deliberative process during convened meetings of the ACUCs. For those meetings, usually held monthly, a quorum (greater than 50% of the voting members) must be present for the ACUC to conduct business. Copies of new or renewal ASPs or amendments are distributed to the ACUC members for their review prior to the convened meeting. It is therefore understood that the 'default' process for ASP review is full committee review, with the expectation that all members are expected to attend and participate in the full committee reviews at the convened ACUC meeting. The members are asked to identify ahead of time any ASPs which they feel must be reviewed and deliberated only by the convened process. It is further understood that any ASP initially subjected to full committee review may require modification and the adequacy of that modification may be assessed by either: (1) return of the modified ASP to the full committee, or (2) in the absence of a call for full committee review, return of the modified ASP to the designated review process.

ACUC members having a conflict of interest with any particular ASP (or amendment) may participate in questions and answers regarding the ASP, but must recuse themselves during deliberation and voting on that action. During that deliberation, the member(s) in conflict of interest must not be counted as part of the quorum, which must still be present to render a decision.

Public Health Service Policy on the Humane Care and Use of Laboratory Animals (PHS Policy) and the Animal Welfare Regulations permit only two methods of protocol (ASP) review.

The convened meeting of the ACUC, as described above

or

the Designated review process: If full committee review is not requested, at least one member of the ACUC, designated by the chairperson and qualified to conduct the review, shall review those research projects and have the authority to approve, require modifications in (to secure approval) or request full committee review of those research projects.

Designated review can be proposed by the ACUC Chair and that process can proceed in the absence of a call by any ACUC member to limit the entire review process to full committee review. Implementation of the designated review process is detailed in the following discussions.

Use of designated review in lieu of a convened meeting.

1. The submitted ASP is pre-reviewed to assure it's readiness for consideration for designated review - submitted ASP determined to adequately address U.S. Government Principles.
2. The ACUC Chair decides if the ASP is ready and should be proposed for review by the designated review.
3. The ACUC Chair appoints, unless pre-defined by ACUC policy, the designated reviewer(s).
4. All ACUC members then receive a copy of the ASP to be reviewed, accompanied by the name(s) of the proposed designated reviewer(s).
5. The ACUC members are given five work days to respond back to the Chair/APD/ACUC Coordinator and indicate one of two dispositions for that ASP:
 - a. They have no objections to that particular ASP being reviewed and potentially approved by the designated review process.
 - b. They call for full committee review (convened meeting) for that particular ASP.
6. Following receipt of responses from the ACUC members (after five work days) and after receipt of responses from at least a quorum of the ACUC members, and in the absence of a call for full committee review, the designated reviewer(s) reviews the ASP and either approves the ASP, returns the ASP to the PI for the purpose of obtaining further information (to secure approval), or directs the ASP for full committee review. The designated reviewer(s) cannot disapprove an ASP - that decision can only be rendered by the full committee.
7. Chair signs and dates the ASP. This denotes the date and finalization of the approval process. Animal ordering and initiation of animal activities described in that ASP/amendment can then proceed.

Using a combination of convened meeting and designated review processes to conduct the approval process for Animal Study Proposals.

1. Copies of each of the proposed ASPs are distributed to the entire ACUC prior to the convened meeting. In this case, it is the 'default' understanding by that ACUC that those ASPs are intended for discussion and probable vote (unless tabled) by the convened ACUC (at least a quorum being present) at the upcoming meeting. The members are asked to identify ahead of time any ASPs which they feel must be reviewed and deliberated only by the convened process (i.e., no shift to designated review.) If any member so identifies, that ASP may not be assigned for designated review as in 2. below.
2. Following discussion by the convened quorum, the ACUC may agree to the following status for a ASP not ready for final approval as presented: the convened quorum agrees it has sufficient information to judge the humane and appropriate animal use aspects of the ASP, but decides additional information/clarification must be furnished before final approval can be granted (the ASP is otherwise approvable). In that case, it is proposed, by the Chair, that the adequacy of the response which furnishes the additional information/clarification will be subsequently judged by the designated review process. The Chair will further identify (unless the ACUC has pre-determined in such cases that the designated review process will always include specified ACUC members) who the designated reviewer(s) will be. The convened quorum is then given the opportunity to call for full committee review of the PI's response; in the absence of such a call, further processing of that ASP will proceed by the designated review process. Following receipt of the additional information, the designated reviewer(s) (acting as one) can: (1) grant final approval for that ASP; (2) request further information/clarification (to secure approval); or (3) return the ASP back for convened ACUC deliberation.

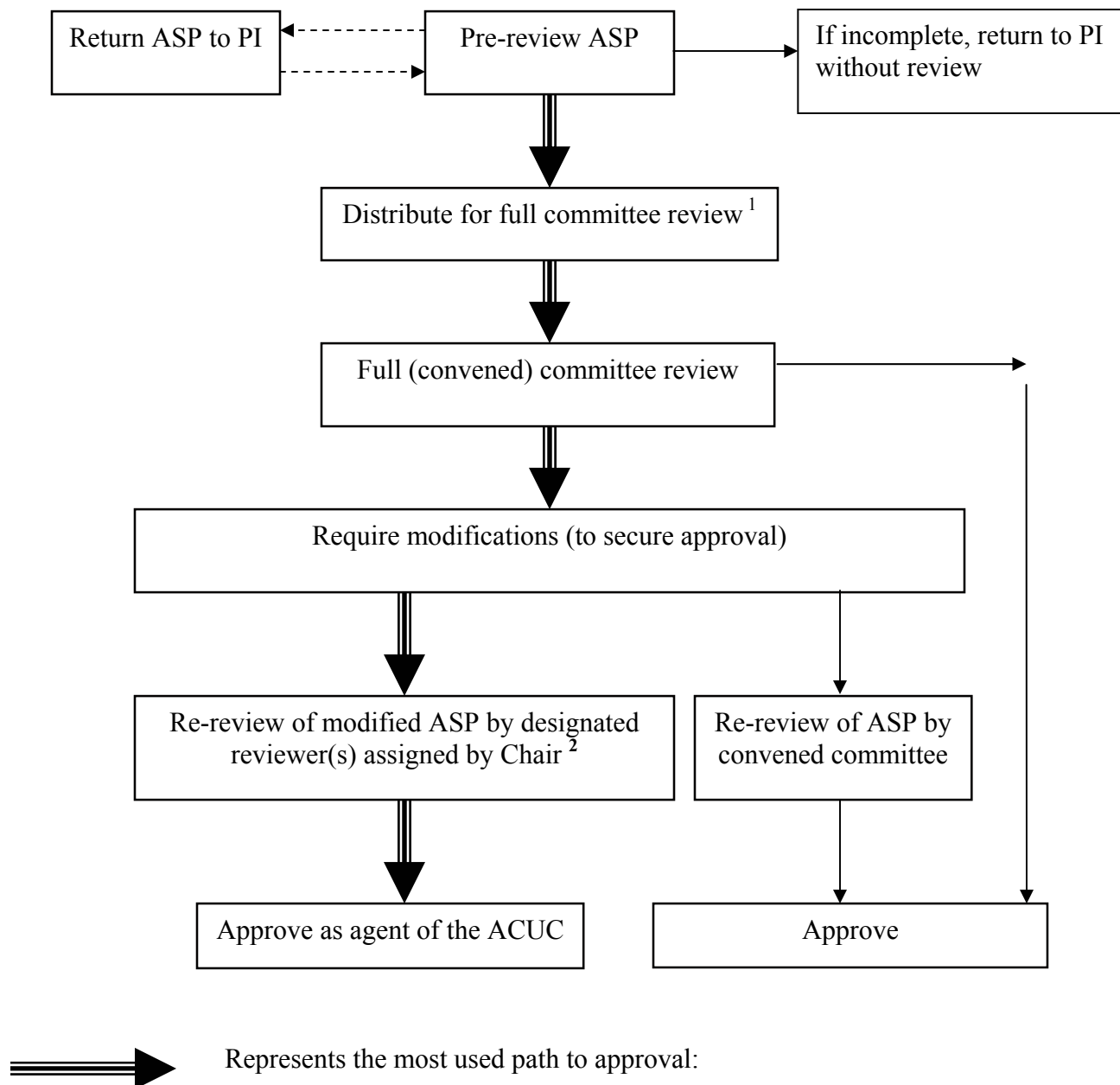
Subsequent actions leading to final approval of ASPs:

1. Chair signs and dates the ASP. This denotes the date and finalization of the approval process. Animal ordering and initiation of animal activities described in that ASP/amendment can then proceed.
2. The following changes may be made to the ASP immediately subsequent to the review and approval process without invoking the designated review process:
 - a. Minor administrative/typographical changes
 - b. Minor changes that were specifically stipulated by the ACUC/designated reviewer(s) (to secure approval) and agreed to by the investigator.

Approved - 12/11/02

ACUC Review Process

Full Committee Review or Full Committee Review with Follow-up Review of Modification by Designated Review



1. It is ARAC policy that ASPs distributed for full committee review that may require modification (to secure approval) may have those modifications reviewed by a designated reviewer(s) unless any ACUC member stipulates that any specific ASPs must only be reviewed/re-reviewed by the full committee.
2. Following review by the convened committee, the modifications to the ASP are not at the level of significant change (see ARAC Guideline for Significant Changes to Animal Study Proposals.)